JUN 8 - 2005

14.510 (K) SUMMARY

Asahi REXEED Series Dialyzers

Manufacturer:

Asahi KASEI Medical Company, Ltd.
9-1, Kanda Mitoshirocho
Chiyoda-ku, Tokyo 101-8482
Japan

Date summary was prepared:

April, 30, 2005

Name(s) of the device:

Asahi REXEED Series Dialyzers

Identification of predicate device(s):

Asahi APS Series Dialyzers
Fresenius Optiflux
Gambro Polyflux

Description of the device:

The line of Asahi REXEED Series Dialyzers (hereinafter called REXEED) is a family of high permeability hollow fiber dialyzers intended for the treatment of patients with acute or chronic renal failure. REXEED-U/S are designed for single use and REXEED-UR/R are designed for reuse. The REXEED dialyers are constructed of reusable hollow fiber (polysulfone) membranes, housed within a plastic casing of styrene butadiene block copolymer and are gamma sterilized prior to shipment.
Modifications made in this 510(k) including the followings. (1) The shape modification of polysulfone hollow fibers to the crimped was implemented. The REXEED dialyzers with crimped hollow fibers is added to the existing APS Series Dialyzers (hereafter called APS) cleared under K001250 and; (2) the REXEED dialyzers membrane surface area ranges from 1.5m^2 to 2.5m^2, while that of APS ranges from 0.8 m^2 to 2.1 m^2 and; (3) mixture of hydrogen peroxide and peroxyacetic acid (e.g., Renalin®) is used as reprocessing agent) and; (4) accordingly, change in the Instruction For Use (IFU) in regard to reprocessing agent.

Intended Use:

The line of the REXEED Series Dialyzers is a family of high permeability hollow fiber dialyzers intended for the treatment of patient with acute or chronic renal failure. REXEED-U/S are intended for single use and REXEED-UR/R for reuse. This is the same intended use as the existing APS cleared under K001250 and K041726, with the exception of using mixture of hydrogen peroxide and peroxyacetic acid (e.g., Renalin®) as reprocessing agent.

Evaluation of Design Modifications

As the basis for Asahi KASEI Medical's device evaluation studies and overall process for managing medical device risk, the company has performed a risk analysis using procedures based on ISO 14971 (2000) "Medical Devices – Application of Risk Management to Medical Devices". The risk analysis method used to assess the impact of the modification was Failure Modes and Effects Analysis (FMEA). Design verification tests based on the result of risk analysis and design input were performed to verify those modifications. All test results meet the acceptance criteria, and proved that those modifications to be appropriate.

Conclusion:

Asahi KASEI Medical made three modifications to the original APS cleared under K001250 and K041726. All design verification tests based on the result of risk analysis and design input proved that the REXEED dialyzers are substantially equivalent in intended use, design, principle of operation, technology, materials, specifications, and performance to the existing APS cleared under K001250 and K041726, Fresenius Optiflux F200A cleared under K003498, and Gambro Polyflux 24S and Polyflux 24R cleared under K010667, with the exception of using mixture of hydrogen peroxide and peroxyacetic acid (e.g., Renalin®).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Asahi Kasei Medical Co., Ltd.
c/o David L. West, Ph.D.
Vice President, Medical Device Development
Quintiles Consulting
1801 Rockville Pike, Suite 300
ROCKVILLE MD 20852

Re: K051187
Trade/Device Name: REXEED Series Dialyzers, Models 15U, 15UR, 18U, 18UR, 21U, 21UR, 25U, 25UR, 15S, 15R, 18S, 18R, 21S, 21R, 25S, and 25R
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI and MSI
Dated: May 9, 2005
Received: May 9, 2005

Dear Dr. West:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051187

16. INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(k) Number:
Device Name: Asahi REXEED Series Dialyzers
Indications for Use:

A. REXEED Series Dialyzers is intended for use for hemodialysis treatment of patients who have chronic or acute renal failure.

B. REXEED Series Dialyzers must be used in accordance with the instructions for a physician familiar with hemodialysis and familiar with the conditions of the patient.

C. REXEED Series Dialyzers have been tested *in vitro* and under single or initial use and REXEED-UR/R Series Dialyzers under reprocessing and reuse conditions for up to 15th use cycles. Based on the results from these evaluations, REXEED-UR/R Series Dialyzers may be reprocessed for reuse on the same patient. If reprocessing and reuse is practiced, it is recommended that the reuse be done under the conditions as existed in the *in vitro* and confirmatory clinical studies as recommended immediately below. It is noted that REXEED-UR/R Series Dialyzers have not been tested for reuse when reprocessed with agents and/or processes other than these, and the performance of the dialyzers under other conditions are not known and cannot be recommended. Accordingly:

(1) The reprocessed dialyzer may be used only if the residual Total Cell Volume (TCV) is at least 80% of the original TCV and if such dialyzer otherwise meets the acceptance criteria of these instruction for use and the instruction of the reprocessing system utilized. Furthermore, the policies, instructions, and criteria of the institution for reuse (e.g., concerning dialyzer performance, residual blood, and/or dialyzer leakage or damage) should be followed.

(2) The reprocessing agent may mixture of hydrogen peroxide and peroxyacetic acid (e.g., Renalin®) in conjunction with the Renatron® Dialyzer Reprocessing System (RS 8300), manufactured by Renal Systems, Inc.

(3) The instructions provided by the manufacturer of the chosen reprocessing agent must be followed in reprocessing the dialyzer.

(4) The reprocessed dialyzer may be used only on dialysis systems equipped with volumetric ultrafiltration controllers.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☑ Prescription Use (per 21 CFR 801.109)

☐ Over-the Counter Use

Colleen Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051187